REMARKS

After entry of the foregoing amendments, claims 20 to 28, 30, 32, 33, and 35 to 39 will be pending. Claim 31 is canceled herein, without prejudice. Claims 20, 33 and 38 are amended to clarify that the active ingredient, the hydrophilic polymer(s) and the pregelatinized starch are in substantially homogeneous admixture. Support for the amendment may be found throughout the specification, for example, at page 13, lines 18 to 20, page 21, line 27 to page 22, line 17, and the description of tablets 1 to 5, on page 24, line 21 to page 26, line 28.

Applicants request entry of the amendments, as they raise no new issues that would require an additional search, and obviate the rejections of record.

The pending claims stand rejected under 35 U.S.C. § 103 over U.S. Patent No. 5,792,477 in view of U.S. Patent No. 5,829,339. Without conceding the correctness of the rejection, Applicants respectfully submit that the amendments to the claims obviate the rejection.

The '477 patent is directed to compositions comprising polymeric microparticles prepared from polymers such as poly(glycolic acid), poly-lactic acid, or copolymers thereof (col. 6, lines 29 to 56). As the Examiner is no doubt aware, and as the '477 patent makes clear, such microparticles are prepared by preparing an emulsion containing a first phase containing the polymer and drug dissolved in a non-aqueous solvent (such as ethyl acetate and benzyl alcohol), and a second, aqueous phase. These phases are then immersed in a quench liquid, to extract solvent from the polymer/drug phase, thereby hardening the polymer/drug droplets into microparticles. (*See id.*)

The '477 patent further teaches that the aqueous phase may contain a surfactant or hydrophilic colloid to the aqueous (continuous) phase, to assist in forming the emulsion, and to help control droplet size. Exemplary surfactants/hydrophilic colloids include carboxymethyl cellulose, poly(vinyl alcohol) and poly(vinylpyrrolidone) (*see* col. 13, lines 60 to 67). As would be readily understood by those of ordinary skill in the art, these surfactants/hydrophilic colloids assist emulsion formation by lining up along the interface between the two surfaces. Since the agents are either hydrophilic or amphiphilic, they do not mix with the non-aqueous, polymer/drug, solvent phase, but only line the surface of the

discontinuous phase droplets. Thus, to the extent such surfactants/hydrophilic colloids end up becoming part of the final microparticles, they would only appear on the surface of the particles, and not in homogeneous admixture with the active ingredient.

The formulations of the present invention, on the other hand, comprise a matrix comprising, as a substantially homogeneous admixture, pregelatinized starch, an active ingredient, and one or more viscous hydrophilic polymers. This matrix is fundamentally different from the microparticles described in the '477 patent, where the active ingredient is not in admixture with either pregelatinized starch or a hydrophilic polymer.

Combining the teachings of the '339 patent fails to resolve this deficiency. Although the '339 patent teaches compositions that may contain pregelatinized starch and hydrophilic polymers, such as HPC and HMPC, even if such ingredients were used in place of the surfactants/hydrophilic colloids described in the '477 patent, the resulting compositions would still not provide a matrix comprising a substantially homogeneous admixture of active ingredient, pregelatinized starch and one or more viscous hydrophilic polymers, as recited in the instant claims. There is simply nothing in the Office Action, nor in the two cited references, that would lead one of ordinary skill in the art to prepare compositions as recited in the instant claims.

Accordingly, Applicants respectfully submit that the claims are in condition for allowance, and request that the rejection under Section 103 be withdrawn. A notice of allowance of all of pending claims 20 to 28, 30, 32, 33, and 35 to 39 is respectfully requested.

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